THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

MEMORANDUM

TO: Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

FROM: Kathleen Sebelius

SUBJECT: Supplemental New Drug Application (NDA 21-998/S002)

DATE: December 7, 2011

On February 7, 2011, Teva Women's Health Inc. submitted to the Food and Drug Administration (FDA) a supplemental new drug application (NDA 21-998/S002) for Plan B One-Step (levonorgestrel 1.5 mg), an emergency contraceptive that can prevent pregnancy if taken within 72 hours of sexual intercourse. The application seeks FDA approval to market Plan B One-Step as a non-prescription drug product without any age restriction. Currently, this drug product, like other FDA-approved (levonorgestrel) emergency contraception drug products, is sold exclusively from behind the pharmacy counter and is available without a prescription only for women ages 17 years and older; women 16 and younger can obtain this drug product only by prescription.

I have carefully considered FDA's Division Director Summary Review of Regulatory Action, dated November 30, 2011, for the supplemental application, which represents the position of the FDA and recommended approval of the application. Based on my review, I have concluded that the data submitted for this product do not establish that prescription dispensing requirements should be eliminated for all ages.[1]

The label comprehension and actual use studies submitted to FDA do not include data on all ages for which the drug would be approved and available over-the-counter. Yet, it is commonly understood that there are significant cognitive and behavioral differences between older adolescent girls and the youngest girls of reproductive age, which I believe are relevant to making this determination as to non-prescription availability of this product for all ages. Although the average age of the onset of menses for girls in the United States is 12.4 years of age, about ten percent of girls reach menarche by 11.1 years of age.[2] If the application is approved, the product would be available, without a prescription or other point-of-sale restrictions, even to the youngest girls of reproductive age.

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[1] *See* 21 C.F.R. § 310.200(b).

[2] Chumlea WC, Schubert CM, Roche AF, Kulin HE, Lee PA, Himes JH, Sun SS: Age at Menarche and Racial Comparisons in U.S. Girls. Pediatrics 2003;111(1): 110-113.

The Federal Food, Drug, and Cosmetic Act provides that "[t]he Secretary [of Health and Human Services], through the Commissioner, shall be responsible for executing" its provisions.[3] As such, I direct FDA to issue a complete response letter because the data submitted for this product are inadequate to support approval in that they do not establish that prescription dispensing requirements should be eliminated for all ages.

[3] 21 U.S.C. § 393(d)(2).